18TH EHEALTH NETWORK 12-13 NOVEMBER 2020, BRUSSELS, BELGIUM

COVER NOTE

8.4 Update on UNICOM project

1. Issue at stake

Most resource-rich countries maintain at least basic national (electronic) repositories and data bases of medicinal products which have gone through the stipulated regulatory national process to be marketed in that national healthcare system. Unfortunately, these uncoordinated national regulatory procedures have resulted in a host of unintended results and impacts endangering patient safety and hindering better healthcare service delivery, particularly in international contexts:

- Across health systems, the same medicinal product may have different names. UMC resource

- Certain dosage strengths or package sizes may also vary or not be available.

- Across countries, the same name may identify a different product with a different active substance.

- Across countries, the number and kind of medicines authorised for national marketing differ very considerably (due to marketing strategies of producers, plus three different marketing authorisation procedures at EU and national levels).

- In cross-border ePrescription (eP) services this necessitates substitution in many, if not the majority of instances – if a specific medicinal product is specified in a prescription.

Similar challenges apply to the electronic recording of medicinal products in other healthcare contexts, e.g. in electronic patient summaries, health records, clinical decision and ordering systems, or ePrescribing software.

Furthermore, the missing univocal identification of medicines hampers timely global pharmacovigilance reporting and warnings. It results in reports on the same active substance and, e.g., its side effects or contraindications, not easily being related to each other permitting health system actors like medical professionals, pharmacists and also patients to identify all medicinal products.

2.   Summary

The UNICOM project is about improved patient safety and better healthcare for all. This European Commission supported innovation action focuses on the implementation of the International Organization for Standardization (ISO) suite of **IDMP** (**ID**entification of **M**edicinal **P**roducts) standards. Work will involve further development, testing, implementation and diffusion of these standards for

- regulatory purposes of national medicinal products authorities and the European Medicines Agency (EMA)

- global pharmacovigilance

- advancing cross-border digital health services, particularly ePrescription

- better healthcare for all, public health services, clinical research, big data analytics, artificial intelligence applications.

Unicom will run for four years. Official start of this innovation action was on 1 December 2019. The project is expected to end on 30 November 2023.

3.   Format of procedure in the meeting

For information.